

REMARKS

Claims 3-13 and 16-19 are pending in the application.

By the foregoing Amendment, claim 19 is amended to broaden the limitation relating to the emitters and the detectors, and to more precisely define the criteria for tinting of the bladder.

These changes are believed not to introduce new matter, and entry of the Amendment is respectfully requested.

Based on the above Amendment and the following Remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections, and withdraw them.

Allowable Subject Matter

Applicant thanks the Examiner for his indication that claims 3, 4, 6, 12, 13, and 16 are allowable.

Rejection under 35 U.S.C. § 101

On page 2 of the Office Action, claim 7 was rejected under section 101 for reciting a positive relationship to the human body. This rejection is traversed on the basis that it is based on a mischaracterization of the claim, is without foundation in statutory or case law, and is in fact contrary to established PTO policy.

In claim 7, the finger is *not* recited as an element of the invention, but rather as a “workpiece,” that is, an article on which the invention operates. Applicant’s counsel is unable to find any authority in case law, or any guidelines in the MPEP, that interprets section 101 to prohibit

recitation of a relationship between the invention and the human body.* On the contrary, issued U.S. patents are replete with claims having limitations similar to that in issue, in which an element of the invention is recited as conforming to some part of the human body. An illustrative sample of these claims is provided in the APPENDIX to this Response.

It is accordingly respectfully submitted that the rejection under section 101 is in error and should be withdrawn.

Rejection under 35 U.S.C. § 112, ¶ 2

On page 2 of the Office Action, claims 5, 7-11, and 17-19 were rejected under section 112, paragraph 2 as being indefinite, on the basis that it is unclear what parameters are to be measured, as recited in claim 19. This rejection is respectfully traversed.

As stated in MPEP 2173.02, “[t]he test for definiteness under 35 U.S.C. 112, second paragraph, is whether ‘those skilled in the art would understand what is claimed when the claim is read in light of the specification.’ *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).”

The application as filed states at paragraph 00015:

The appendage [which is to be inserted into the bladder of the cuff in accordance with the invention] can be a finger (more specifically, a fingertip), an arm, or any other appendage having one or more physiological parameters normally measured by an inflatable cuff device.

* If the Examiner is aware of any case law or guidelines in the MPEP, the Examiner is respectfully requested to provide citations therefor.

At paragraph 0002, the application states:

Inflatable cuff devices are used in a variety of applications to measure such parameters as volume, change in volume, pressure, response to pressure, occlusion, and response to occlusion. See, for example, U.S. Patent Nos. 4,747,415 and 5,692,520 to Lavoisier. These measurements are used widely in, but not limited to, the medical community to assay physiological parameters. Examples of such physiological parameters are blood pressure, cardiac cycle (plythsmography), blood flow, and pulse rate, to name a few.

Paragraph 0004 references the prior art devices of U.S. Patent Nos. 4,202,347 and 4,331,155 to Sacks, U.S. Patent No. 5,025,793 to Richley et al., and U.S. Patent No. 5,218,966 to Yamasawa, in which a bladder inflates against the finger. These devices are all used to measure systolic and diastolic blood pressures.

It is therefore respectfully submitted that a person of ordinary skill in the art at the time the application was filed would have understood “physiological parameters being measured other than volume or change in volume” as recited in claim 19, when read in light of the specification, to include (although not necessarily to be limited to) pressure, response to pressure, occlusion, and response to occlusion, for the assay of physiological parameters such as physiological parameters are blood pressure, cardiac cycle (plythsmography), blood flow, and pulse rate.

Under the guidelines set forth in MPEP 2173.02, “physiological parameters being measured other than volume or change in volume” as recited in claim 19 meets the requirement for definiteness, and the rejection should be withdrawn.

Rejections under 35 U.S.C. § 103

On page 3 of the Office Action, claims 5, 7-11, and 17-19 were rejected under section 103(a) as being unpatentable over Geddes et al in view of Itonaga et al. To the extent the Examiner may consider this rejection to be applicable to claim 19 as amended, and to claims 5, 7-11, 17, and 18 depending therefrom, it is respectfully traversed as being based upon references that do not teach or suggest the claimed invention.

In the Office Action, Geddes et al. was characterized as teaching all the elements of claim 19 except the location of the emitters and detectors and tinting of the bladder. Itonaga et al. was cited as teaching both the location of the emitters and detectors and tinting of the bladder.

As set forth in the Declaration of David Bell submitted herewith, the Geddes et al. patent describes an inflatable pressure cuff for measurement of systolic, mean, and diastolic pressure; oxygen saturation; pulse; and respiratory rate. At column 2, line 2 and column 3, line 51, Geddes et al. describes the inflatable cuff 46 as being “optically transparent.” Geddes et al. states at column 3, lines 32-39:

In order to facilitate use of the cuff on a bone-containing body member, i.e., to avoid bone shadow, two light sources 40 and 42 are circumferentially spaced on one housing section in opposition to a photodetector 44 mounted on the other housing section. This configuration increases the transmission of light through the tissue bed around the bone 45 in the member in which blood pressure is measured noninvasively.

Geddes et al. further states at column 3, lines 58-60, that the inflatable cuff 46 is “made of material that is transparent to the wavelengths of light emitted by the LEDs.” In other words, Geddes et al.’s cuff 46 is substantially completely transparent.

The Office Action characterizes Itonaga et al. as teaching of a black bladder for minimizing interference and light piping. The Itonaga et al. patent states at column 6, lines 40-46:

Another way to implement the windows would be to make outer cuff 2A black and reinforce its surface. Then outer cuff 2A would have low infrared transparency, and slits 20 could be provided in the portions of the cuff facing pulse sensors 10. This would make it difficult for stray light to strike the photodetectors in pulse sensors 10 and so would enhance their pulse detection function.

According to the Declaration of Dr. Bell, to a person of ordinary skill in the art, making the cuff black implies that it opaque; although as it is not physically possible to make an object perfectly opaque, it will have some nominal transparency. In his opinion, it is to this nominal transparency that Itonaga et al. refers in stating that the cuff, if black, “would have low infrared transparency.” In other words, Itonaga et al.’s outer cuff 2A is substantially completely opaque.

As Dr. Bell points out, although it would be possible to make Geddes et al.’s cuff 46 black as taught by Itonaga et al., this change would Geddes et al.’s device inoperative for its intended purpose, as an opaque cuff 46 would substantially impede the transmission of light through the tissue bed around the bone 45 in the member in which blood pressure is measured. In light of such inoperability, one of ordinary skill in the art would not be motivated to make Geddes et al.’s cuff 46 black as taught by Itonaga et al..

Further, Geddes et al.'s cuff 46 and Itonaga et al.'s outer cuff 2A teach an "all or nothing" approach to transparency and opacity, with Geddes et al.'s cuff 46 being substantially completely transparent and Itonaga et al.'s outer cuff 2A being substantially completely opaque. A cuff that is either substantially completely transparent as taught by Geddes et al. or substantially completely opaque as taught by Itonaga et al. cannot (1) absorb the specific wavelengths of light emitted by the emitters to damp light piping but also allow for sufficient transmission of light through the cuff into and out of the appendage to properly illuminate the tissue and to properly detect the light back-scattered from the appendage; or (2) achieve attenuation such as to decrease the intensity of the piped light to below the governing SNR of the detectors.

Neither Geddes et al. nor Itonaga et al. teaches the bladder being made from a material tinted with pigments selected such that the bladder material will absorb the specific wavelengths of light emitted by the emitters to damp light piping but also allow for sufficient transmission of light through the cuff into and out of the appendage to properly illuminate the tissue and to properly detect the light back-scattered from the appendage; or the bladder being made from a material tinted with pigments selected such that the bladder material also will achieve attenuation such as to decrease the intensity of the piped light to below the governing SNR of the detectors. Therefore, as Dr. Bell concludes, even if Geddes et al.'s cuff 46 were made black as taught by Itonaga et al., the invention as disclosed and claimed in the present application would not result.

In view of the foregoing, it is respectfully submitted that the invention as recited in claim 19 as amended, and to claims 5, 7-11, 17, and 18 depending therefrom, is patentable over Geddes et al in view of Itonaga et al.; and that the rejection should be withdrawn.

Conclusion

All rejections have been complied with, properly traversed, or rendered moot. Thus, it now appears that the application is in condition for allowance. Should any questions arise, the Examiner is invited to call the undersigned representative so that this case may receive an early Notice of Allowance.

Favorable consideration and allowance are earnestly solicited.

Respectfully submitted,

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Attachments: (1) Declaration Under 37 C.F.R. § 1.132 Of David Bell
(2) Appendix (U.S. Patent Claims Reciting Conformity To A Human Body Part)